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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY-DOCKET NO.
08/913,960	01/02/98	MURRER	21,737,778, 21,737,779, 21,737,780, 21,737,781, 21,737,782, 21,737,783, 21,737,784, 21,737,785, 21,737,786, 21,737,787, 21,737,788, 21,737,789, 21,737,790, 21,737,791, 21,737,792, 21,737,793, 21,737,794, 21,737,795, 21,737,796, 21,737,797, 21,737,798, 21,737,799, 21,737,800, 21,737,801, 21,737,802, 21,737,803, 21,737,804, 21,737,805, 21,737,806, 21,737,807, 21,737,808, 21,737,809, 21,737,810, 21,737,811, 21,737,812, 21,737,813, 21,737,814, 21,737,815, 21,737,816, 21,737,817, 21,737,818, 21,737,819, 21,737,820, 21,737,821, 21,737,822, 21,737,823, 21,737,824, 21,737,825, 21,737,826, 21,737,827, 21,737,828, 21,737,829, 21,737,830, 21,737,831, 21,737,832, 21,737,833, 21,737,834, 21,737,835, 21,737,836, 21,737,837, 21,737,838, 21,737,839, 21,737,840, 21,737,841, 21,737,842, 21,737,843, 21,737,844, 21,737,845, 21,737,846, 21,737,847, 21,737,848, 21,737,849, 21,737,850, 21,737,851, 21,737,852, 21,737,853, 21,737,854, 21,737,855, 21,737,856, 21,737,857, 21,737,858, 21,737,859, 21,737,860, 21,737,861, 21,737,862, 21,737,863, 21,737,864, 21,737,865, 21,737,866, 21,737,867, 21,737,868, 21,737,869, 21,737,870, 21,737,871, 21,737,872, 21,737,873, 21,737,874, 21,737,875, 21,737,876, 21,737,877, 21,737,878, 21,737,879, 21,737,880, 21,737,881, 21,737,882, 21,737,883, 21,737,884, 21,737,885, 21,737,886, 21,737,887, 21,737,888, 21,737,889, 21,737,890, 21,737,891, 21,737,892, 21,737,893, 21,737,894, 21,737,895, 21,737,896, 21,737,897, 21,737,898, 21,737,899, 21,737,900, 21,737,901, 21,737,902, 21,737,903, 21,737,904, 21,737,905, 21,737,906, 21,737,907, 21,737,908, 21,737,909, 21,737,910, 21,737,911, 21,737,912, 21,737,913, 21,737,914, 21,737,915, 21,737,916, 21,737,917, 21,737,918, 21,737,919, 21,737,920, 21,737,921, 21,737,922, 21,737,923, 21,737,924, 21,737,925, 21,737,926, 21,737,927, 21,737,928, 21,737,929, 21,737,930, 21,737,931, 21,737,932, 21,737,933, 21,737,934, 21,737,935, 21,737,936, 21,737,937, 21,737,938, 21,737,939, 21,737,940, 21,737,941, 21,737,942, 21,737,943, 21,737,944, 21,737,945, 21,737,946, 21,737,947, 21,737,948, 21,737,949, 21,737,950, 21,737,951, 21,737,952, 21,737,953, 21,737,954, 21,737,955, 21,737,956, 21,737,957, 21,737,958, 21,737,959, 21,737,960, 21,737,961, 21,737,962, 21,737,963, 21,737,964, 21,737,965, 21,737,966, 21,737,967, 21,737,968, 21,737,969, 21,737,970, 21,737,971, 21,737,972, 21,737,973, 21,737,974, 21,737,975, 21,737,976, 21,737,977, 21,737,978, 21,737,979, 21,737,980, 21,737,981, 21,737,982, 21,737,983, 21,737,984, 21,737,985, 21,737,986, 21,737,987, 21,737,988, 21,737,989, 21,737,990, 21,737,991, 21,737,992, 21,737,993, 21,737,994, 21,737,995, 21,737,996, 21,737,997, 21,737,998, 21,737,999

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HM42/0911

JONES, D EXAMINER

ART UNIT	PAPER NUMBER
16	

09/11/98

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/913,960

Applicant(s)
Murrer et al.

Examiner
Dwayne C. Jones

Group Art Unit
1614



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 and 6-8 is/are rejected.

☒ Claim(s) 5 and 9 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Claims

1. Claims 1-9 are pending.
2. Claims 1-4, 6-8 are rejected.
3. Claims 5 and 9 are objected to.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

5. The drawings filed September 25, 1997 are approved by the Office Draftsperson, see enclosed copy of PTO FORM 948.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

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7. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- © Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Objections

8. Claims 5 and 9 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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10. Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Even though claims 5 and 9 are objected to and claim 6 is rejected they will be included in the following rejections in order to advance prosecution of this application.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 6 provides for the use of lanthanum carbonate for the treatment of hyperphosphataemia, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

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parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 9 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yanagihara et al. Yanagihara et al. teach the skilled artisan of a lanthanum carbonate, specifically $\text{La}_2(\text{CO}_3)_3 \cdot 5\text{H}_2\text{O}$, (see line 1 of Table 2, on page 226 and lines 4-9 on page 228).

17. Claim 9 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mineely et al. Mineely et al. teach of $\text{La}_2(\text{CO}_3)_3 \cdot 3\text{H}_2\text{O}$, (see abstract).

18. Claim 9 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mzareulishvili et al. Mzareulishvili et al. teach of $\text{La}_2(\text{CO}_3)_3 \cdot 6\text{H}_2\text{O}$, (see abstract).

19. Claim 9 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Oda. Oda teaches of $\text{La}_2(\text{CO}_3)_3 \cdot n\text{H}_2\text{O}$ where the variable of n is equal to 1, 3, 5 and 8, (see abstract).

20. Since the invention of claim 9 is a product-by-process, the following rejections under 35 U.S.C. 102(b) are supported by the ensuing explanations. The invention defined in a product-by-process claim is a product, not a process. In re Bridgeford, 357 F2d 679, 149 U.S.P.Q. 55

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(CCPA 1966). It is the patentability of the product claimed and NOT of the recited process steps which must be established. In re Brown, 459 F2d 531, 173 U.S.P.Q. 685 (CCPA 1972); In re Wertheim, 541 F2d, 191 U.S.P.Q. (CCPA 1976). A comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning the patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Junji of JP 62145024. Junji discloses of an immobilizing agent for the phosphate ion which is composed of a carbonate of a rare earth element, such as Lanthanum, (see abstract). Moreover, Junji teaches that since these compounds immobilize phosphate ions, these compounds can be used to treat hyperphosphatemia. The claims differ from the reference by reciting a specific species and a more limited genus than the reference. Moreover, the determination of dosage having the optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. However, it would have been obvious to one having ordinary skill in the art at the time of

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the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

23. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagihara et al. Yanagihara et al. teach the skilled artisan of a lanthanum carbonate, specifically $\text{La}_2(\text{CO}_3)_3 \cdot 5\text{H}_2\text{O}$, (see line 1 of Table 2, on page 226 and lines 4-9 on page 228). Even though these claims are directed to pharmaceutical compositions with the intended use, the prior art reference of Yanagihara et al. do teach of $\text{La}_2(\text{CO}_3)_3 \cdot 5\text{H}_2\text{O}$ and when this compound is combined with water, these pharmaceutical claims are rendered obvious to one having ordinary skill in the art to make pharmaceutical preparations simply with the incorporation of the pharmaceutically acceptable carrier of water.

24. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mineely et al. Mineely et al. teach of $\text{La}_2(\text{CO}_3)_3 \cdot 3\text{H}_2\text{O}$, (see abstract). Even though these claims are directed to pharmaceutical compositions with the intended use, the prior art reference of Yanagihara et al. do teach of $\text{La}_2(\text{CO}_3)_3 \cdot 3\text{H}_2\text{O}$ and when this compound is combined with water, these pharmaceutical claims are rendered obvious to one having ordinary skill in the art to make pharmaceutical preparations simply with the incorporation of the pharmaceutically acceptable carrier of water.

25. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mzareulishvili et al. Mzareulishvili et al. teach of $\text{La}_2(\text{CO}_3)_3 \cdot 6\text{H}_2\text{O}$, (see abstract). Although these claims are

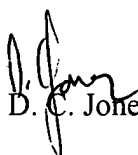
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directed to pharmaceutical compositions with the intended use, the prior art reference of Mzareulishvili et al. do teach of $\text{La}_2(\text{CO}_3)_3 \cdot 6\text{H}_2\text{O}$ and when this compound is combined with water, these pharmaceutical claims are rendered obvious to one having ordinary skill in the art to make pharmaceutical preparations simply with the incorporation of the pharmaceutically acceptable carrier of water.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. C. Jones

September 4, 1998